

## Office Action Summary

Application No.

10/530,351

Applicant(s)

BOUCHERIE, BART GERARD

Examiner

Monica A. Huson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-30 is/are pending in the application.
- 4a) Of the above claim(s) 17-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 040605.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This office action is in response to the paper filed 27 June 2007.

#### ***Election/Restrictions***

Applicant's election of claims 1 and 3-16 in the reply filed on 27 June 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 17-30 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 27 June 2007.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 3, the phrase "or the like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiba (WO 01/70311), using a translation of the related document JP 2001-259031. Regarding Claim 1, Chiba shows that it is known to carry out a method of manufacturing plungers for medical syringes (para. 0001), said plunger comprising at least two parts including a longitudinal plunger body (Figure 1, element 5) made of plastic and a piston body provided at

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the front end of the plunger body (Figure 1, element 6), which piston body comprises a plastic which is softer than the plastic of the plunger body (para. 0011-0013), wherein said plunger or at least part of the plunger is formed by first manufacturing the piston and then the plunger body by means of injection molding, and wherein the plunger body is injected against the piston body, the piston being formed free of any flash lines (Figure 1; para. 0016-0018).

Regarding Claim 3, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein the piston body and the plunger body are connected solely by adhesion between the plastics out of which they are made, without any meshing parts (Figure 1, para 0018).

Regarding Claim 4, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein at least one inwardly directed part is formed on the piston body and use is made during injection molding of a mold part having a protruding part in which one or several lateral recesses are provided, such that the mold part may be removed from the piston body due to the elastic flexibility of the piston body (Figure 5; para. 0002-0004; it is interpreted that the mold part will be the negative image of the molded body- when the piston has a inwardly directed part, the mold part will have a protrusion to form the inwardly directed part).

Regarding Claim 5, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein the plastic forming the piston body is provided in a respective mold cavity via the back side of the piston body to be formed (Figure 2(c)).

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Jentzen (U.S. Patent 5,782,803). Jentzen shows that it is known to carry out a method for manufacturing plungers for medical syringes having at least a piston body comprising forming a part of the piston body at the location of the piston body which protrudes frontally from a front side of the piston body and which, when the plunger is located in a syringe, can penetrate at least partially through an outlet of the syringe (Figures 4-6; Column 3, lines 41-50), wherein the piston body part is formed of a material which is different from the material of the piston body, and herein the materials for forming the piston body and the protruding portion are formed with known processes (e.g. injection) such that the piston body can be made in one piece with a plunger body belonging to the plunger (Figure 7, element 300, 202).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiba, in view of Sorensen (U.S. Patent 5,030,406).

Regarding Claim 6, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show multicavity molding. Sorensen shows that it is known to carry out a multicavity molding process wherein one article is formed in a first mold after which the article, while it is still held in a first part, is presented to a second mold cavity in which a second element of the article is then injected against the first article by means of injection molding, and wherein the mold cavities are of the desired final article shape, and the two plastics are connected to each other due to adhesion between the plastics (Figures 1-8). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Sorensen's multistep/multicavity molding process during Chiba's molding method in order to most efficiently form two parts of an article at the same time.

Regarding Claim 7, Chiba shows the process as claimed as discussed in the rejection of Claim 6 above, but he does not show simultaneously forming a second portion of the article at the same time as a first portion. Sorensen shows that it is known to carry out a method wherein the second body is formed such that it connects to first body, a subsequent first body is simultaneously being formed by means of a connector nozzle with which the first body is formed but in another mold cavity (Figures 1-8). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Sorensen's multistep/multicavity molding process during Chiba's molding method in order to most efficiently form two parts of an article at the same time.

Claim 8 is rejected under 35 USC 103(a) as being unpatentable over Chiba. Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, including a method wherein the plunger body is formed in a mold, after which a mold part with the plunger body in it is presented against other mold parts in which the piston body is formed (Figures 2(a)-2(c); para. 0015). Although Chiba's process molds the plunger first and then the piston, It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to mold the piston first followed by the plunger because selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. (*In re Burhaus*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946)).

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Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiba, in view of Schwartz (U.S. Patent 3,659,749).

Regarding Claim 9, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show an accessory at a front side of the piston body. Schwartz shows that it is known to carry out a method of manufacturing a piston and plunger including forming a plunger and an accessory located at a front side of the piston body, wherein the accessory is made of a different material than the piston (Figure 3, element 42). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's accessory during Chiba's method in order to provide an intermixing syringe (see Schwartz, Column 2, lines 14-18).

Regarding Claim 10, Chiba shows the process as claimed as discussed in the rejection of Claim 9 above, but he does not show using an accessory. Schwartz shows using an accessory, wherein its material comprises glass (Column 3, lines 61-63; it is being interpreted that glass can be considered a plastic material of sorts since it can be melted and reshaped and molded again). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's harder material for the accessory during Chiba's method in order to provide an intermixing syringe (see Schwartz, Column 2, lines 14-18).

Regarding Claim 11, Chiba shows the process as claimed as discussed in the rejection of Claim 9 above, but he does not show using an accessory. Schwartz shows that it is known to carry out a plunger/piston manufacturing method including an accessory which comprises a part which extends frontally of a front side of the piston and which, when the plunger is situated in the syringe, can at least partially penetrate an outlet of the syringe (Figure 8, element 112, 117; Column 6, lines 3-44; it is noted that the remaining limitation of the claim is being considered solely as intended use). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's accessory during Chiba's molding method in order to provide a one-way valve in the plunger/piston assembly (See Schwartz, Column 6, lines 3-5).

Regarding Claim 12, Chiba shows the process as claimed as discussed in the rejection of Claim 9 above, but he does not show using an accessory. Schwartz shows that it is known to make a plunger/piston assembly including an accessory comprising a part which enables creation of a passage between the front side and a rear side of the piston body when emptying the syringe (Column 6, lines 3-44; it is noted that the remaining limitation of the claim is being considered solely as intended use). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's accessory during Chiba's

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molding method in order to provide a one-way valve in the plunger/piston assembly (See Schwartz, Column 6, lines 3-5).

Regarding Claim 13, Chiba shows the process as claimed as discussed in the rejection of Claim 9 above, but he does not show using an accessory. Schwartz shows that it is known to carry out a method of making a plunger/piston assembly including an accessory made as a separate part provided on a front side of the piston body (Figure 14). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Schwartz's accessory during Chiba's molding method in order to provide a one-way valve in the plunger/piston assembly (See Schwartz, Column 6, lines 3-5).

Claims 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiba, in view of Reynolds (U.S. Patent 4,861,335).

Regarding Claim 14, Chiba shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show connecting the piston to the plunger at a later stage. Reynolds shows that it is known to carry out a method of forming a piston and a plunger, wherein the piston is attached to the plunger at a later stage after molding of the plunger and part of the piston (Column 4, lines 56-68). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Reynolds' attachment process during Chiba's molding method in order to enable the attachment of various pistons to the end of the same plunger.

Regarding Claim 15, Reynolds shows the process as claimed as discussed in the rejection of Claim 1 above, but he does not show connecting the plunger to a drive element. Reynolds shows that it is known to carry out a method wherein the plunger cooperates with an associated drive element (Column 5, lines 57-68; Column 6, lines 1-3, 20-54). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use Reynolds' drive element in combination with Chiba's plunger in order to accurately move and position the plunger during consumer use.

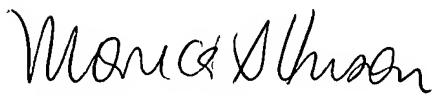
### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A. Huson whose telephone number is 571-272-1198. The examiner can normally be reached on Monday-Friday 7:00am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read "Monica A. Huson". The signature is fluid and cursive, with the first name "Monica" being more prominent than the last name "Huson".

Monica A Huson

August 14, 2007